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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,221	03/07/2001	Paul Sanberg	C14-135	5403

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/801,221	SANBERG ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *87-91 and 93-98*.

   Claim(s) withdrawn from consideration: *112-123*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Anne-Marie Falk

Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit: 1632

Continuation of 5. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

The reply does not represent a complete response to the final rejection. Claims 112-123 are directed to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

At page 6, paragraph 2 of the response, Applicants assert that the claims are not directed to methods of therapy and that the cells derived by the claimed methods are at least useful for generating and isolating proteins produced at various stages of neural cell differentiation, and for permitting recombinant production of polypeptides. However, the specification does not teach how to use the resulting cell compositions produced by the claimed methods to prepare proteins as Applicant suggests. Since the cell compositions produced are heterogeneous cell populations, the skilled artisan would not find that there exists a well established utility to use the cell compositions to prepare proteins. Applicants further assert that the cells generated are enabled for at least therapeutic research. However, a utility such as this does not rise to the level of a credible, specific and substantial utility within the meaning of 35 U.S.C. 101 because it is not a real world utility and therefore does not meet the criteria for a specific and substantial utility. The only utility asserted in the specification that rises to the level of a credible, specific and substantial utility within the meaning of 35 U.S.C. 101 is to use the resulting cell compositions in therapeutic transplantation. Thus, enablement is evaluated for the sole asserted utility. However, the specification does not teach how to use the cell compositions produced by the claimed methods in therapeutic transplantation.

Thus, Claims 87-91 and 93-98 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record.

At page 8, paragraph 4 of the response, Applicants assert that the amendments overcome the rejection under 35 U.S.C. 112, second paragraph. However, the amendment to Claim 87 now recites "in comparison to an umbilical cord blood progenitor cell that has not been cultured in the presence of the differentiation agent." Thus, any progenitor cell within the cord blood can be used for the comparison. However, only a single or a few different types of progenitor cells will actually be differentiated to the cell of interest, by way of contact with "an effective amount of differentiation agent for a period sufficient to differentiate the progenitor cell to a cell of interest." Given the limited disclosure of the specification, it is unclear how the skilled artisan would use unrelated cord blood progenitor cells for the claimed comparison.

Thus, Claims 87-91 and 93-98 remain rejected under 35 U.S.C. 112, second paragraph, for reasons of record.

At pages 8-9 of the response, Applicants assert that the rejections of Claims 99-111 are moot in view of the cancellation of those claims. Accordingly, the rejections set forth under 35 U.S.C. 102 are withdrawn in view of the cancellation of Claims 99-111.